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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,235	ANGELETTI ET AL.	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Currently, Claims 23-44 are pending. Claims 23-44 are examined on the merits. Claims 1-22 are canceled.

The Amendments filed on Nov. 12, 2008 has been received and entered.

Election/Restrictions

Applicant's election with traverse of the species XAD-4 in the reply filed on Nov. 29, 2007 is acknowledged.

Claim Objections

Claim 36 is objected to because of the following informalities:

In Claim 36, there should be no space between "non aqueous."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 23, the phrase "such that" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

In Claim 34, the term "low" percentage is indefinite because it is unclear what oxygen concentrations are considered "low" percentage.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 23-24, 26-28, 31, 34, 36, 37, 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Grape Seed Extract White Paper (http://www.activin.com/Testing%20White%20paper__.html) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Grape Seed Extract White Paper teaches the riches sources of proanthocyanidins in nature are grape seed from wine grapes (Vitis vinifera). Grape seed extracts are poor source of monomers, ranging from 1 to 30%, compared to green tea extracts, which contain significantly higher levels of more beneficial monomers at a

much lower cost than do the grape seed extracts. Green tea extracts are not the best sources of OPCS (page 3, paragraph 1). Seeds used in the manufacture of grape seed extracts can be acquired from either grape juice operations of from wine producers after they have been discarded from the winemaking process (page 3, Seed Management, paragraphs 1 and 3). The most important aspect of seed management is the drying, separating and storage. Seeds used to manufacture grape seed extracts are separated from the macerated skin and immediately subject to the extraction process. White grape seeds are removed from the juice prior to fermentation and retain a significant greater portion of their polyphenols. Several methods of drying are commonly used, including sun drying or mechanical drying using ovens or kilns. The seeds must be stored properly to prevent mildew or oxidation. Improperly stored seeds have been known to rapidly lose their potency and render them useless for extraction purposes. By removing excess moisture and minimizing their exposure to oxidizing elements (oxygen), grape seeds can be stored for prolonged periods of time, while maintaining their OPC potency (page 4, paragraphs 2, 4-5). Extraction with water and ethanol, where the solvents are then recovered and the resulting concentrate is then either spray dried or vacuum dried and ground to final specifications (page 4, Seed Processing). Grape seed extract is qualitatively separated by thin layer chromatography (page 5, Methods of Analysis), HPLC (page 10), Gel permeation Chromatography (page 10).

Applicant argues that the reference did not disclose a process of separating seeds from pomace.

In response to Applicant's argument, the reference teaches seeds used to manufacture grape seed extracts are separated from the macerated skin and immediately subject to the extraction process. White grape seeds are removed from the juice prior to fermentation and retain a significant greater portion of their polyphenols (page 4, paragraph 2, 4-5). Seeds inherently are contained in grape flesh and skin; thus, to get the seeds, the grape flesh and skin, known as pomace, will have to be removed immediately.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 23-25, 27-37, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grape Seed Extract White Paper (http://www.activin.com/Testing%20White%20paper__.html) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Grape Seed Extract White Paper teaches the riches sources of proanthocyanidins in nature are grape seed from wine grapes (Vitis vinifera). Grape seed extracts are poor sourced of monomers, ranging from 1 to 30%, compared to green tea extracts, which contain significantly higher levels of more beneficial monomers at a much lower cost than do the grape seed extracts. Green tea extracts

are not the best sources of OPCS (page 3, paragraph 1). Seeds used in the manufacture of grape seed extracts can be acquired from either grape juice operations of from wine producers after they have been discarded from the winemaking process (page 3, Seed Management, paragraphs 1 and 3). The most important aspect of seed management is the drying, separating and storage. Seeds used to manufacture grape seed extracts are separated from the macerated skin and immediately subject to the extraction process. White grape seeds are removed from the juice prior to fermentation and retain a significant greater portion of their polyphenols. Several methods of drying are commonly used, including sun drying or mechanical drying using ovens or kilns. The seeds must be stored properly to prevent mildew or oxidation. Improperly stored seeds have been known to rapidly lose their potency and render them useless for extraction purposes. By removing excess moisture and minimizing their exposure to oxidizing elements, grape seeds can be stored for prolonged periods of time, while maintaining their OPC potency (page 4, paragraphs 2, 4-5). Extraction with water and ethanol, where the solvents are then recovered and the resulting concentrate is then either spray dried or vacuum dried and ground to final specifications (page 4, Seed Processing). Grape seed extract is qualitatively separated by thin layer chromatography (page 5, Methods of Analysis), HPLC (page 10), Gel permeation Chromatography (page 10). However it does not teach organic cultivation and the temperature, humidity, ethanol-water ratio, drug-liquor ratio, pressure.

The reference does not specifically teach performing the process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure claimed by

applicant. The process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Organic sources of grape seed would be an obvious substitute for grape seeds cultivated with herbicide and pesticide because grape seed extracts have been reported to prevent chemical and environmental pollutant toxicity (page 1, paragraph 2). Thus, an artisan of ordinary skill would reasonably expect that using organic source of grape seed could be used as the types grape seeds to prevent chemical and environmental pollutant toxicity taught by the reference. This reasonable expectation of success would motivate the artisan to use organic source of grape seed in the reference composition. Thus, using organic source of grape seed is considered an obvious modification of the reference.

Applicant argues that the reference did not disclose a process of separating seeds from pomace.

In response to Applicant's argument, the reference teaches seeds used to manufacture grape seed extracts are separated from the macerated skin and immediately subject to the extraction process. White grape seeds are removed from the juice prior to fermentation and retain a significant greater portion of their polyphenols (page 4, paragraph 2, 4-5). Seeds inherently are contained in grape flesh and skin; thus, to get the seeds, the grape flesh and skin, known as pomace, will have to be removed immediately.

Claims 23-25, 27-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grape Seed Extract White Paper (http://www.activin.com/Testing%20White%20paper__.html) as applied to claims 23-25, 27-37, 40 above, and further in view of Cuomo et al. (US 6358542 B2) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Grape Seed Extract White Paper teaches the riches sources of proanthocyanidins in nature are grape seed from wine grapes (Vitis vinifera). Grape seed extracts are poor sourced of monomers, ranging from 1 to 30%, compared to green tea extracts, which contain significantly higher levels of more beneficial monomers at a much lower cost than do the grape seed extracts. Green tea extracts

are not the best sources of OPCS (page 3, paragraph 1). Seeds used in the manufacture of grape seed extracts can be acquired from either grape juice operations of from wine producers after they have been discarded from the winemaking process (page 3, Seed Management, paragraphs 1 and 3). The most important aspect of seed management is the drying, separating and storage. Seeds used to manufacture grape seed extracts are separated from the macerated skin and immediately subject to the extraction process. White grape seeds are removed from the juice prior to fermentation and retain a significant greater portion of their polyphenols. Several methods of drying are commonly used, including sun drying or mechanical drying using ovens or kilns. The seeds must be stored properly to prevent mildew or oxidation. Improperly stored seeds have been known to rapidly lose their potency and render them useless for extraction purposes. By removing excess moisture and minimizing their exposure to oxidizing elements, grape seeds can be stored for prolonged periods of time, while maintaining their OPC potency (page 4, paragraphs 2, 4-5). Extraction with water and ethanol, where the solvents are then recovered and the resulting concentrate is then either spray dried or vacuum dried and ground to final specifications (page 4, Seed Processing). Grape seed extract is qualitatively separated by thin layer chromatography (page 5, Methods of Analysis), HPLC (page 10), Gel permeation Chromatography (page 10). However it does not teach organic cultivation and the temperature, humidity, ethanol-water ratio, drug-liquor ratio, pressure, XAD-4.

Cuomo et al. teaches solid matrix can be any material having a stronger affinity for at least some of the antioxidant components than for the aqueous phase. The solid

matrix material is a polymeric adsorbent material resin of Amberlite XAD-4 (column 7, lines 47-67).

Grape Seed Extract White Paper teaches method to extract proanthocyanidins, which are antioxidative elements (page 1, paragraph 1). Cuomo et al. teaches XAD-4 can be used to purify antioxidants (see discussion above). Thus, it would be obvious to use XAD-4 to isolate antioxidants, such as that taught by grape seed extracts. An artisan of ordinary skill would clearly expect that the XAD-4 taught by Cuomo et al. would function successfully to isolate the antioxidant taught by Grape Seed Extract White Paper. This reasonable expectation of success would motivate the artisan to modify the method of grape seed extraction to include a XAD-4 column as an effective means to extract the grape seed extract.

The reference does not specifically teach performing the process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure claimed by applicant. The process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure to use in order to best

achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Organic sources of grape seed would be an obvious substitute for grape seeds cultivated with herbicide and pesticide because grape seed extracts have been reported to prevent chemical and environmental pollutant toxicity (page 1, paragraph 2). Thus, an artisan of ordinary skill would reasonably expect that using organic source of grape seed could be used as the types grape seeds to prevent chemical and environmental pollutant toxicity taught by the reference. This reasonable expectation of success would motivate the artisan to use organic source of grape seed in the reference composition. Thus, using organic source of grape seed is considered an obvious modification of the reference.

Applicant argues the extract does not have a higher content of polyphenols.

In response to Applicant's argument, Grape Seed Extract White Paper teaches the riches sources of proanthocyanidins in nature are grape seed from wine grapes (Vitis vinifera). Grape seed extracts are poor sourced of monomers, ranging from 1 to 30% (page 3, paragraph 1). Therefore, after the column purification, polyphenols content would still be higher than that of monomers.

Claims 23-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grape Seed Extract White Paper (http://www.activin.com/Testing%20White%20paper__.html) and Cuomo et al. (US

6358542 B2) as applied to claims 23-25, 27-40 above, and further in view of Schulman et al. (US 4609110) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Grape Seed Extract White Paper teaches the riches sources of proanthocyanidins in nature are grape seed from wine grapes (Vitis vinifera). Grape seed extracts are poor sourced of monomers, ranging from 1 to 30%, compared to green tea extracts, which contain significantly higher levels of more beneficial monomers at a much lower cost than do the grape seed extracts. Green tea extracts are not the best sources of OPCS (page 3, paragraph 1). Seeds used in the manufacture of grape seed extracts can be acquired from either grape juice operations of from wine producers after they have been discarded from the winemaking process (page 3, Seed Management, paragraphs 1 and 3). The most important aspect of seed management is the drying, separating and storage. Seeds used to manufacture grape seed extracts are separated from the macerated skin and immediately subject to the extraction process. White grape seeds are removed from the juice prior to fermentation and retain a significant greater portion of their polyphenols. Several methods of drying are commonly used, including sun drying or mechanical drying using ovens or kilns. The seeds must be stored properly to prevent mildew or oxidation. Improperly stored seeds have been known to rapidly lose their potency and render them useless for extraction purposes. By removing excess moisture and minimizing their exposure to oxidizing elements, grape seeds can be stored for prolonged periods of time, while

maintaining their OPC potency (page 4, paragraphs 2, 4-5). Extraction with water and ethanol, where the solvents are then recovered and the resulting concentrate is then either spray dried or vacuum dried and ground to final specifications (page 4, Seed Processing). Grape seed extract is qualitatively separated by thin layer chromatography (page 5, Methods of Analysis), HPLC (page 10), Gel permeation Chromatography (page 10). However it does not teach organic cultivation and the temperature, humidity, ethanol-water ratio, drug-liquor ratio, pressure, XAD-4, the seed separator.

Cuomo et al. teaches solid matrix can be any material having a stronger affinity for at least some of the antioxidant components than for the aqueous phase. The solid matrix material is a polymeric adsorbent material resin of Amberlite XAD-4 (column 7, lines 47-67).

Schulman et al. teaches an apparatus to provide for separation of seed particles (column 4, lines 44-55), where the spacing between the gap may be regulated in correlation with the type of fruit for effective seed separation, such as grapes (column 6, lines 36-41). Thus, an artisan of ordinary skill would reasonably expect that isolating grape seeds be a seed separator could be used as the types of method to separate seeds from grapes in order to extract antioxidants from grape seed as taught by the references (see discussion above). This reasonable expectation of success would motivate the artisan to use a seed separator in the reference method. Thus, using a seed separator to isolate grape seeds is considered an obvious modification of the references.

Grape Seed Extract White Paper teaches method to extract proanthocyanidins, which are antioxidative elements (page 1, paragraph 1). Cuomo et al. teaches XAD-4 can be used to purify antioxidants (see discussion above). Thus, it would be obvious to use XAD-4 to isolate antioxidants, such as that taught by grape seed extracts. An artisan of ordinary skill would clearly expect that the XAD-4 taught by Cuomo et al. would function successfully to isolate the antioxidant taught by Grape Seed Extract White Paper. This reasonable expectation of success would motivate the artisan to modify the method of grape seed extraction to include a XAD-4 column as an effective means to extract the grape seed extract.

The reference does not specifically teach performing the process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure claimed by applicant. The process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal process in the temperature, humidity, ethanol-water ratio, drug-liquor ratio and pressure to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results

from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Organic sources of grape seed would be an obvious substitute for grape seeds cultivated with herbicide and pesticide because grape seed extracts have been reported to prevent chemical and environmental pollutant toxicity (page 1, paragraph 2). Thus, an artisan of ordinary skill would reasonably expect that using organic source of grape seed could be used as the types grape seeds to prevent chemical and environmental pollutant toxicity taught by the reference. This reasonable expectation of success would motivate the artisan to use organic source of grape seed in the reference composition. Thus, using organic source of grape seed is considered an obvious modification of the reference.

Applicant argues that the references did not disclose a process of separating seeds from pomace.

In response to Applicant's argument, the reference teaches seeds used to manufacture grape seed extracts are separated from the macerated skin and immediately subject to the extraction process. White grape seeds are removed from the juice prior to fermentation and retain a significant greater portion of their polyphenols (page 4, paragraph 2, 4-5). Seeds inherently are contained in grape flesh and skin; thus, to get the seeds, the grape flesh and skin, known as pomace, will have to be removed immediately. Schulman et al. teaches an apparatus to provide for separation of seed particles (column 4, lines 44-55), where the spacing between the gap may be

regulated in correlation with the type of fruit for effective seed separation, such as grapes (column 6, lines 36-41).

Applicant argues that the references do not teach the claimed process and resulting product.

In response to Applicant's argument, Grape Seed Extract White Paper teaches the riches sources of proanthocyanidins in nature are grape seed from wine grapes (Vitis vinifera). Grape seed extracts are poor sourced of monomers, ranging from 1 to 30% (page 3, paragraph 1). Therefore, after the column purification, polyphenols content would still be higher than that of monomers.

Applicant argues that the concentration, temperature, humidity, ethanol-water ratio, drug-liquor ration, pressure parameters are not one of ordinary skill in the art would optimize.

In response to Applicant's argument, Applicant's claim is drawn to dried grape seeds that are extract in ethanol to obtain polyphenols that have low monomer content. Grape Seed Extract White Paper teaches the riches sources of proanthocyanidins in nature are grape seed from wine grapes (Vitis vinifera). Grape seed extracts are poor sourced of monomers, ranging from 1 to 30% (page 3, paragraph 1). The most important aspect of seed management is the drying, separating and storage. Seeds used to manufacture grape seed extracts are separated from the macerated skin and immediately subject to the extraction process. White grape seeds are removed from the juice prior to fermentation and retain a significant greater portion of their polyphenols. Several methods of drying are commonly used, including sun drying or mechanical

drying using ovens or kilns. The seeds must be stored properly to prevent mildew or oxidation. Improperly stored seeds have been known to rapidly lose their potency and render them useless for extraction purposes. By removing excess moisture and minimizing their exposure to oxidizing elements, grape seeds can be stored for prolonged periods of time, while maintaining their OPC potency (page 4, paragraphs 2, 4-5). Extraction with water and ethanol, where the solvents are then recovered and the resulting concentrate is then either spray dried or vacuum dried and ground to final specifications (page 4, Seed Processing). Grape seed extract is qualitatively separated by thin layer chromatography (page 5, Methods of Analysis), HPLC (page 10), Gel permeation Chromatography (page 10). Cuomo et al. teaches solid matrix can be any material having a stronger affinity for at least some of the antioxidant components than for the aqueous phase. The solid matrix material is a polymeric adsorbent material resin of Amberlite XAD-4 (column 7, lines 47-67). Schulman et al. teaches an apparatus to provide for separation of seed particles (column 4, lines 44-55). Thus one of ordinary skill in the art would know that in order to obtain polyphenols from grape seeds, the seeds would have to be kept dry to prevent fermentation or spoilage; ethanol to water concentration would have to be determine in order to get polyphenols; concentrated polyphenols would need be resuspended in a liquor for column chromatography. Since the starting material, grape seed, already has higher polyphenol than monomer content, the subsequent purification of polyphenols would lead to more polyphenols than monomer content.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 41, 44 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sun et al. (1999, J Chromatography A, 841, 115-121).

Sun et al. teaches grapes (Vitis vinifera) seeds are removed by hand from the grapes, washed with distilled water, drained, blotted with filter paper, air-dried at 25 degree Celsius in the dark for one day and stored at minus 20 degree Celsius under nitrogen until use (page 116, Experimental, Preparation of Seeds). The frozen seeds were ground finely under liquid nitrogen and immediately extracted using methanol-water (80:20, v/v), supernatants were evaporated to remove solvents, fractionated on

LiChroprep RP-18 column and stored until needed (page 116, Experimental, Preparation of the phenolic extract). Each procyanidin, a type of polyphenol, isolated by HPLC reach purity higher than 96% (page 121, left column, paragraph 1).

The claims are drawn to a grape seed extract composition comprising greater than 70% polyphenol as the active ingredient therein, within a product-by-process claim.

The cited reference teaches a composition (including food additive) consisting of (or consisting essentially of) an aqueous extract of grape seed as the active ingredient therein which appears to be identical to (and thus anticipate) the presently claimed grape seed extract composition (including inherently comprising the instantly claimed levels of procyanins, since both were prepared using similar aqueous extraction (including the same essential temperature heating range) and concentration steps, and chromatography steps. Consequently, the instantly claimed grape seed extract composition appears to be anticipated by the cited reference.

In the alternative, even if the claimed grape seed extract composition is not identical to the referenced grape seed extract composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced grape seed extract composition is likely to inherently possess the same characteristics of the claimed grape seed extract composition particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed grape seed extract composition would have been obvious to those of ordinary skill in the art within the meaning of USC 103. Further, if not anticipated, the result-effective adjustment of particular conventional

working conditions (e.g., food additive for oral consumption) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Please note that the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether the levels of grape seed extract anthocyanins within Applicant's grape seed extract differ and, if so, to what extent, from the levels within the grape seed extract disclosed by the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the Applicants.

Please also note that "the patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 218 USPQ 289, 292 (Fed. Cir. 1983).

Claims 41-42, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (1999, J Chromatography A, 841, 115-121) and Food for live cells (http://web.archive.org/web/20010306033028/http://food4livecells.com/pr_art20.htm).

Sun et al. teaches grapes (Vitis vinifera) seeds are removed by hand from the grapes, washed with distilled water, drained, blotted with filter paper, air-dried at 25 degree Celsius in the dark for one day and stored at minus 20 degree Celsius under nitrogen until use (page 116, Experimental, Preparation of Seeds). The frozen seeds were ground finely under liquid nitrogen and immediately extracted using methanol-water (80:20, v/v), supernatants were evaporated to remove solvents, fractionated on LiChroprep RP-18 column and stored until needed (page 116, Experimental, Preparation of the phenolic extract). Each procyanidin, a type of polyphenol, isolated by HPLC reach purity higher than 96% (page 121, left column, paragraph 1). However, it does not teach green tea extract.

Food for live cells teaches grape seed extract and green tea extract are powerful antioxidants (page 1, Features). The capsules is best taken with meals as a food additive (page 2, How to use AIM Proancynol 2000 TM).

Sun et al. teaches grapes (Vitis vinifera) seeds extract and Food for live cells teaches grape seed extract and green tea extract are powerful antioxidants (page 1, Features). Thus, an artisan of ordinary skill would reasonably expect that green tea extract could be used as the types antioxidants with grape seed extracts taught by the references. This reasonable expectation of success would motivate the artisan to use

green tea extract with grape seed extract in the reference composition. Thus, using green tea extract is considered an obvious modification of the references.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ashraf-Khorassani et al. (2004, J Agric Food Chem, 52, 2440-2444).

Ashraf-Khorassani et al. teaches grape seed were crushed and extracted at 100% CO2 at 9500 psi and 80 degree Celsius to remove grape oil from seeds (page 2441, Results and Discussion, paragraph 1). Stopping fermentation of seeds are intrinsically taught because a seed supplying company, Synthon, Inc., will not allow seeds to spoil when stored or before being sold (see page 2440, Experimental Procedures, Sample Preparations). Thus, the seeds will have to be separated from the pomace before before being dried for storage.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/
Primary Examiner, Art Unit 1655